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Prevalence of Bacterial Vaginosis and Fetal and Maternal outcome in a Teritiary Hospital, Chennai.

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ABSTRACT

BACTERIAL VAGINOSIS is a clinical syndrome resulting from replacement of the normal hydrogen peroxide producing Lactobacillus species in the vaginal flora with high concentrations of anaerobic bacteria (e.g., Prevotella sp. and Mobiluncus sp.), G. vaginalis, Ureaplasma, Mycoplasma, and numerous fastidious or uncultivated anaerobes. Thus bacterial vaginosis is truly polymicrobial in nature.

Results: The study was conducted in 314 women with active labour. The mean age at enrollment was 24.8+/-3.66. The maternal age did not differ between the subjects with bacterial vaginosis and women without bacterial vaginosis.

The prevalence of bacterial vaginosis is 18% in women at active labour. There is significant association of various factors like socio economic status, maternal weight, birth weight and neonatal complications with bacterial vaginosis. The association of bacterial vaginosis with preterm labour is quiet significant. Maternal age and parity lacked significant association with bacterial vaginosis.

Amsel's criteria has almost perfect agreement with Nugent's scoring system. But clue cells alone or clue cells combined with amine test can replace the cumbersome three parameters Amsel's scoring system or technically demanding Nugent's scoring system.

KEYWORDS Bacterial Vaginosis, Amsel"s criteria and Nugents scoring system.

Introduction:

BACTERIAL VAGINOSIS is a clinical syndrome resulting from replacement of the normal hydrogen peroxide producing Lactobacillus species in the vaginal flora with high concentrations of anaerobic bacteria (e.g., Prevotella sp. and Mobiluncus sp.), G. vaginalis, Ureaplasma, Mycoplasma, and numerous fastidious or uncultivated anaerobes. Thus bacterial vaginosis is truly polymicrobial in nature.

These microbial changes may be transient in some women, whereas others may have these changes for longer intervals of time. Among women seeking medical care in reproductive years , bacterial vaginosis is the most prevalent cause of vaginal discharge or malodor. Most women with bacterial vaginosis are asymptomatic.

Adverse pregnancy outcomes, including premature rupture of membranes, preterm labor, preterm birth, intra-amniotic infection, and postpartum endometritis have been associated with symptomatic bacterial vaginosis. Treatment of bacterial vaginosis in pregnant women can reduce the signs and symptoms of vaginal infection. Oral therapy for bacterial vaginosis can reduce the risk of late miscarriage. There are more and more studies supporting that such therapy decreased adverse outcomes in the neonates4.

Diagnostic Considerations

Bacterial vaginosis can be diagnosed by the use of clinical criteria (i.e., Amsel's Diagnostic Criteria) or Gram stain (Nugent's scoring).Amsel's clinical criteria include four parameters namely characteristic vaginal discharge, presence of clue celss, high vaginal Ph and positive amine test. Presence of at least three parameters establishes Bacterial vaginosis

A Gram stain (considered the gold standard laboratory method for diagnosing bacterial vaginosis) is used to determine the relative concentration of lactobacilli (i.e., long Gram-positive rods), Gram-negative and Gram-variable rods and cocci (i.e., G. vaginalis, Prevotella, Porphyromonas, and peptostreptococci), and curved Gram-negative rods (i.e., Mobiluncus) characteristic of bacterial vaginosis.

Culture of G. vaginalis is not recommended as a diagnostic tool because it is not specific because of polymicrobial nature of bacterial vaginosis. Cervical Pap tests have no clinical utility for the diagnosis of bacterial vaginosis because of their low sensitivity and specificity.

PCR has been used in research settings for the detection of a variety of organisms associated with bacterial vaginosis. But the evaluation is being done on its clinical utility. Detection of specific organisms like Atopobium vaginae might be predictive of bacterial vaginosis by PCR. Additional validation is needed before these tests can be recommended to diagnose bacterial vaginosis.

Treatment

Currently there is consensus that all symptomatic pregnant women with bacterial vaginosis should be treated with antibiotics. Oral therapy include metronidazole and topical therapy include 0.75% metronidazole gel and 2% clindamycin cream.

WHO issued guidelines about antibiotic usage in pregnancy for bacterial vaginosis in 2011.

Recommended regimen for pregnant women

- Metronidazole 250mg three times daily for 7 days after first trimester
- Metronidazole 2g orally as a single dose if treatment is imperative in first trimester.

Alternate regimen

Metronidazole 2 gram orally as a single dose or
Clindamycin 300mg twice daily for 7 days or
Metronidazole 0.75% gel, 5gram intravaginally twice daily for 7 days.

PRIMARY OBJECTIVE:

- To estimate the prevalence of bacterial vaginosis in women presenting with labour.

SECONDARY OBJECTIVES:

1. To assess the association between bacterial vaginosis and various maternal correlates.
2. To assess the association between bacterial vaginosis and

adverse fetal outcomes.

To assess the utility of Amsel's criteria and its components against the gold standard Nugent's criteria

SAMPLE SIZE:
The reported prevalence of bacterial vaginosis varies from 9% to 23 %. Studies conducted in India in socio economically diverse population revealed a prevalence ranging from of 8.6% to 20%. Indu Lata ,Sujatha et al. in 2010 found a prevalence of 20% 200 women studied. Vatsala Dadhwal ,Roopa Hariprasad established a prevalence of 8.6% in pregnant women coming for antenatal checkups. Zemenu Mengiste et al., reported a prevalence of 19.8% in antenatal women attending antenatal care in Ethiopia.
Expecting a prevalence of 15% in our study population with 95% confidence interval falling within 4% on either side of our estimate, the calculated sample size is around 306. We included 314 subjects in our study fulfilling the inclusion and exclusion criteria.

Results and Discussion.

Diagnostic accuracy of combination of two of Amsel's Criteria

Statistic	Vaginal Discharge And High Vaginal pH	Vaginal Discharge And Amine Test	Vaginal Discharge And Clue Cells	High Vaginal pH And Amine Test	High Vaginal pH And Clue Cells	Amine Test and Clue cells	Positive Amsel
Apparent Prevalence	10%	12%	13%	10%	12%	16%	17%
True Prevalence	18%	18%	18%	18%	18%	18%	18%
Sensitivity	45%	62%	68%	52%	62%	80%	88%
Specificity	98%	98%	98%	99%	99%	98%	98%
Positive Predictive Value	83%	90%	90%	94%	95%	92%	92%
Negative Predictive Value	89%	92%	93%	90%	92%	96%	97%
Positive Likelihood Ratio	23.04	40.31	43.77	66.80	80.62	51.83	56.44
Negative Likelihood Ratio	0.56	0.38	0.33	0.49	0.38	0.2	0.13

Among the two criteria tests, the combination of amine test and clue cells is coming close to the Amsel's Criteria. Now it is interesting to explore these two parameters to combine the other two parameters namely characteristic vaginal discharge and high vaginal pH.

- 314 women in active labor were included in the study. Of these, 102 women belonged to preterm labor group.
- The prevalence bacterial vagiosis is 18% as detected by gold standard Nugent's scoring.
- Distribution of maternal age did not differ between women with bacterial vaginosis and women without bacterial vaginosis. (p=0.4226)
- The prevalence of bacterial vaginosis did not differ between primigravid and multigravid women. (p=0.32)
- Women in class 5 of socio economic status had higher prevalence of bacterial vaginosis than women in class 4. (p=0.02047)
- Neonatal complications like prematurity, birth asphyxia and sepsis are more common in women with bacterial vaginosis than in women without bacterial vaginosis. (p=0.00002)
- Bacterial vaginosis is more commonly associated with preterm labour than term labour. (p=0.003387)
- Birthweight of babies born to mother with bacterial vaginosis is lesser than birth weight of babies born to mother without bacterial vaginosis. (difference in mean=160g, p=0.041)
- Average weight of mothers with bacterial vaginosis is lesser than that of women without bacterial vaginosis. (difference in mean=1.9 kg , p=0.009232)
- The amsel's scoring system has almost perfect agreement with Nugent's scoring criteria. (cohen's kappa=0.8779).
- Among the individual components of Amsel' criteria, clue cells alone has the best sensitivity (91%) and specificity (98%) and better positive likelihood ratio (39.16).
- When two components of Amsel's criteria is considered , combination of positive amine test and clue cells has the best sensitivity (80%) and better specificity (98%) and positive likelihood ratio (51.83).
- Combination of amine test and clue cells has also perfect agreement with Nugent's scoring. (cohen's kappa=0.8286).
- Bed side whiff's test and wet mount preparation of vaginal fluid for clue cells under light microscope can replace Amsel's criteria and technically demanding Nugent's scoring system.

Conclusion:
The prevalence of bacterial vaginosis is 18% in women at active labour. There is significant association of various factors like socio economic status, maternal weight, birth weight and neonatal complications with bacterial vaginosis. The association of bacterial vaginosis with preterm labour is quiet significant. Maternal age and parity lacked significant association with bacterial vaginosis.

Amsel's criteria has almost perfect agreement with Nugent's scoring system. But clue cells alone or clue cells combined with amine test can replace the cumbersome three parameters Amsel's scoring system or technically demanding Nugent's scoring system.

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